Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
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Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

Our Ref: **FOI2026/00481**

1 June 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 30 April 2026. You wrote:

> *'Under the Freedom of Information Act 2000, I am requesting copies of all MHRA Good Manufacturing Practice (GMP) inspection reports conducted from 1 January 2025 to the present for the following NHS organisations:*
>
> * *Imperial College Healthcare NHS Trust*
> * *Royal Free London NHS Foundation Trust*
> * *Royal Devon University Healthcare NHS Foundation Trust*
> * *South Tees Hospitals NHS Foundation Trust*
> * *Barking, Havering & Redbridge University Hospitals NHS Trust*
> * *Barts Health NHS Trust*
> * *Manchester University NHS Foundation Trust*
> * *St George's University Hospitals NHS Foundation Trust*
> * *London North West University Healthcare NHS Trust*
> * *NHS Greater Glasgow and Clyde*
>
> *For each organisation, please provide:*
>
> * *Full MHRA GMP inspection reports (2025–present)*
> * *Any associated deficiency reports, CAPAs, or compliance letters*
> * *Any follow-up correspondence relating to inspection outcomes*

MHRA Response

Under Section 14(1) of the FoI Act, public authorities are not obliged to comply with a request which is deemed vexatious. By way of clarification, it is the request which is treated as vexatious, not the person making the request.

A request may be treated as vexatious, if the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on the organisation.

A vexatious request is assessed with reference to all the circumstances of an individual case. There are four broad themes to consider when looking at whether an FoI request(s) is vexatious. These four themes are:

1. the burden (on the public authority and its staff);
2. the motive (of the requester);
3. the value or serious purpose (of the request); and
4. any harassment or distress (of and to staff).

These four broad themes are not a checklist, and they are not exhaustive they simply emphasise that a range of factors need to be considered when apply Section 14(1).

In this case, the Agency is treating your request as vexatious due to the burden on the public authority and its staff.

This request concerns 10 NHS sites over almost 18 months. Before we release inspection reports and the other requested documents, MHRA have to consider redactions which are made to discrete pieces of information within the reports. This is a manual process and a rapid / automated method to complete this process does not exist. Due to the risk of human error, QA check also takes place on the draft redactions, which while necessary, nonetheless places an additional burden on our resources.

To answer the request for correspondence, MHRA would have to seek third-party representations with the NHS trusts on any correspondence between the MHRA and sites requested. In this instance, this would require consulting with multiple NHS trusts and negotiating any redactions they may require under exemptions referring to one or more sections of the FoI Act.

We recognise the public interest in requests regarding the NHS but believe that answering this request would place a disproportionate burden on staff. The redaction and third party consultation would impede staff from other work at MHRA, affecting our ability to conduct inspection activities and respond to other queries. In summary, answering this request would take staff away from vital day to day work impacting public and patient safety issues.

On this basis, the Agency has decided that due to the burden required to answer this request, Section 14(1) of the FoI Act applies on this occasion.

Advice and assistance

To be as helpful as possible, we can provide advice to help narrow your request. In this instance, we suggest excluding the request for 'any follow-up correspondence relating to inspection outcomes' due to the burden of third-party consultations and redactions. If this is not acceptable, we suggest requesting for 3 – 5 NHS sites at a time.

Please note for any further requests that where inspections are not yet finalised, documentation cannot be released. When these reports are requested, Section 43(2) is engaged to withhold the inspection report in full because the inspection findings are currently subject to an on-going regulatory procedure. The report may include omissions or inaccuracies that, if released, would be likely to cause commercial harm. We perceive the public interest to be best served by with-holding the report until the regulatory procedure is finalised. The report would then be available to request through FOI.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/